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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,674	02/23/2004	Stephen T. Kuehn	S16.12-0135	1936
27367 7590 10/18/2007 WESTMAN CHAMPLIN & KELLY, P.A. SUITE 1400 900 SECOND AVENUE SOUTH MINNEAPOLIS, MN 55402-3319			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,674	Applicant(s) KUEHN ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 28 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 28, 41, 42 and 45-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 36-40, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/23/04, 11/26/04, 5/15/06, 10/4/06, 9/17/07.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 21 and 36-40 in the reply filed on July 30, 2007 is acknowledged. The traversal is on the ground(s) that the species as elected includes, in addition to at least one gripper, one leaflet fastener applicator. This is found to be persuasive, and in a voice mail from Hallie Finucane, Reg. No. 33,172, on October 4, 2007, a provisional election was made without traverse to prosecute also the sub-species (i.e., a leaflet fastener applicator) shown in figure 19A, claims 43 and 44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28, 41, 42, and 45-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 39, it is not certain how

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the plunger can be moved along a shaft "to push leaflets toward the plunger." Did the Applicant intend the leaflets to be pushed towards the grasper?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,395,367). Wilk discloses, at least in figures 5 and 7 and in col. 8, lines 48-55 and col. 9, line 44 to col. 10, line 55; a device including a catheter (32), a gripper (35a), and a leaflet fastener applicator (36a or one of "staplers" and "suture applicators"), where the fastener applicator and the gripper extend from separate shafts (35, 36) that extend simultaneously through the catheter, where the gripper extends through a first catheter (unlabeled sleeve of 35) and the fastener applicator extends through a second catheter (unlabeled sleeve of 36).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 36 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Harrison et al. (5,306,326). Wilk discloses the invention substantially as claimed. Wilk discloses a device including a catheter and a leaflet fastener applicator (36a) with two opposing jaws passing through the catheter, such that an actuating element (36c) projecting from the proximal end of the catheter (32). However, Wilk does not disclose that the catheter has suitable dimensions for insertion into a heart and that a fastener projects from the distal end of the catheter, or that one of the jaws has a site for holding a tack and a second jaw has a site for holding a cap.

With respect to the catheter dimensions: It would have been a matter of obvious design choice to size the catheter as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to the fastener projecting from the distal end of the catheter or jaws respectively holding a tack and a cap: Harrison et al. teach, at least in figures 8A-9 and in col. 7, line 24 to col. 8, line 30; a device including a fastener (staple 54 or tack 90) projecting from the distal end (at 68 or 66) of a catheter (80), and that one of the jaws

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(66) has a site for holding a tack (90) and a second jaw (66) has a site for holding a cap (96). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison et al., to include a fastener projecting from the distal end of the catheter, or a jaws having a site for holding a tack and a second jaw having a site for holding a cap, in the device of Wilk. Such modifications would allow the device to laparoscopically fasten tissues or repair wounds within a patient's abdominal wall or internal organ.

8. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Hathaway et al. (5,304,184). Wilk discloses the invention substantially as claimed. Wilk discloses a device including a gripper, where the gripper may be one of several instruments (e.g., "hook," "biopsy forceps," "suction devices," "staplers, suture applicators and clamps"). However, Wilk does not disclose that the gripper includes a grasper and a plunger, where the plunger can be moved along one of the separate shafts toward the grasper, and where the plunger comprises arms to push the leaflets towards the grasper. Hathaway et al. teach, at least in figures 17a-17d and in col. 10, line 56 to col. 11, line 4; a gripper that is a laparoscopic suture applicator including a grasper (53) and a plunger (62) with arms (57) that can push tissue towards the grasper. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply the gripper of Hathaway et al. with Wilk's device. Such a device would allow a laparoscopic, suture-based method of tissue wound closure without the need for other devices or therapeutic materials and

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without the necessity of direct visualization of a tissue opening, which is to be closed by the suture applicator.

9. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of Harrison et al. as applied to claim 43 above, and further in view of Bolanos et al. (5,423,858). Wilk in view of Harrison et al. discloses the invention substantially as claimed. Wilk in view of Harrison et al. discloses a device with opposing jaws respectively holding a tack and a cap. However, the combination does not disclose a slot in the jaw for holding a tack. Bolanos et al. teach, at least in figures 4 and 6 and in col. 5, lines 3-20; a device including jaws having slots (60) for respectively holding a tack (120) and a cap (130). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bolanos et al., to modify the jaws of the device of Wilk in view of Harrison et al., such that they have slots for at least holding a tack. Such a slot would accommodate and engage the head (92) of tack 90 and would allow improved mechanical support for the tack as it held by the jaw and as it is driven into tissue.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bradley et al. (5,374,275) teach a device with a grasper and a plunger with arms..

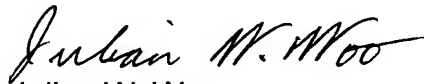
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

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4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

October 15, 2007